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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,817

Applicant(s)

LUMAUIG, ROMMEL C.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-16 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Information Disclosure Statement***

The information disclosure statement filed 4/1/03 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance for PN 5279526, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The corrections have been noted.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,10-12,15,23 are rejected under 35 U.S.C. 102(b) as being anticipated by Miraki (5951513). Fig. 3 shows a balloon catheter with an outer tubular member **20a** and an inner tubular member **22a** with the tubular members being partially attached by two junctures **24a**. Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). A juncture is interpreted as something providing means to join two things. Therefore, the inner and outer tubular members can be characterized as being bonded. Fig. 2 shows the elongated shaft with inflation lumen **23a** and the junctures are located along the same

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length of the catheter. Fig. 1 shows the catheter system with cross section 3-3 taken proximal to the balloon, this is the view for Fig. 3. It can also be seen that the balloon **14a** is on the distal shaft section. With respect to claim 12, Fig. 3 is a symmetrical view, thus the junctures are disposed equal distance from one another. The balloon is fully capable of being configured for a stent.

Claims 1, 10-12, 15, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sirhan et al. (WO 93/20882). Fig. 18 shows a balloon catheter with an outer tubular member **13** and an inner tubular member **11** with the tubular members having two secured portions formed by the inner surface of the outer tubular member being bonded to the outer surface of the inner tubular member. Fig. 1 shows the elongated shaft with inflation lumen **20** and the secured portions are located along the same length of the catheter. It can also be seen that the balloon **16** is on the distal shaft section. With respect to claim 12, Fig. 18 illustrates the secured portions are disposed radially at an equal distance from one another. The balloon is fully capable of being configured for a deployable device.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (WO 93/20882). Sirhan et al. is explained supra. However, Sirhan does not disclose the secured portions having a longitudinal dimension ranging 1-4mm or radial dimension ranging 0.5-3mm or spacing the secured portion from the balloon

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proximal end about 1mm. It would have been an obvious matter of design choice to use a longitudinal dimension or radial dimension for the secured portions having dimensions of 1-4mm or 0.5-3mm respectively, since applicant has not disclosed that the longitudinal dimension or radial dimension for the secured portions provide any advantage or solve any stated problem or are used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the longitudinal dimension or radial dimensions taught by Sirhan et al. or the claimed range 1-4mm and 0.5-3mm respectively, because both longitudinal and radial dimensions still function to attach or bond the tubular elements together and provide separate lumens. Increasing or decreasing the lumen dimensions would have been obvious to vary depending on the desired capabilities with respect to using the lumens for increasing or decreasing inflation pressure or also the amount of fluid a lumen can handle. Regarding claims 7,8 it would have been an obvious matter of design choice to space the secured portions at a range of 1-3mm from the balloon, since applicant has not disclosed that the spacing provides any advantage or solves any stated problem or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the spacing taught by Sirhan et al. or the claimed range 1-3mm, because both spacings still separate the expansion area from the inflation area.

Claims 13,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. in view of Muni et al. (5533968). Sirhan et al. is explained supra. However, Sirhan does not disclose the outer and inner tubular members being made of

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different materials. Muni et al. teach that outer and inner tubular members of a balloon catheter are made of different material and are bonded by heat, col. 11, lines 16-32. It would have been obvious to one of ordinary skill in the art to use different materials for the tubular members as taught by Muni in the balloon catheter of Sirhan in order to strengthen the bond.

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. in view of Brown (6096056). Sirhan et al. is explained supra. However, Sirhan does not disclose the use of a stent on the intermediate portion of the balloon. Brown teaches (Fig. 3) a stent 18 on a balloon catheter in the intermediate region. The intermediate region is interpreted as the expanding portion. It would have been obvious to one of ordinary skill in the art to use a stent with the balloon catheter of Sirhan et al. in order to provide a patient with a device to maintain the vessel lumen.

Response to Arguments

Applicant's arguments filed 4/1/03 have been fully considered but they are not persuasive. In response to Applicant's argument that the Miraki catheter includes additional structure (webs) not required by Applicant's invention, it must be noted that Miraki discloses the invention as claimed. The fact that it discloses additional structure not claimed is irrelevant to the issue of patentability.

Conclusion

Applicant's amendment and Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 4/1/03, 5/1/03 prompted the new ground(s) of rejection presented in this Office action.

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Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino TC 3700, AU 3738
20-June-03



Bruce Snow Primary Examiner

